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Date of mailing (day/month/year) 09 February 1999 (09.02.99)	in its capacity as elected Office
International application No. PCT/EP97/03099	Applicant's or agent's file reference 97/08217 WO
International filing date (day/month/year) 13 June 1997 (13.06.97)	Priority date (day/month/year)
Applicant SABEL, Bernhard, A. et al	
1. The designated Office is hereby notified of its election made X in the demand filed with the International Preliminary 13 January 199 in a notice effecting later election filed with the International Preliminary 2. The election X was was not was not was not was not was not was 2.2(b).	Examining Authority on: 99 (13.01.99) ational Bureau on:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

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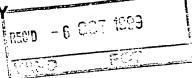
Eugénia Santos

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicants	or age	nt's file reference			ication of Transmittal o	
97/0821	7 WO		FOR FURTHER AC	Preliminary Examination Report (Form PCT/IPEA/416)		
International application No. International filing date (day/month/year) Priority date (day/month/year)				month/year)		
PCT/EP	97/03	099	13/06/1997		13/06/1997	none
Internation A61K9/5		nt Classification (IPC) or na	tional classification and IPC			
AO INS/S						
Applicant						
MEDING	OVA N	IEDICAL CONSULTIN	IG GMBH et al.			
		ational preliminary exam smitted to the applicant a	ination report has been paccording to Article 36.	prepared by this In	ternational Prelimin	ary Examining Authority
2. This	REPO	RT consists of a total of	5 sheets, including this	cover sheet.		
	oeen a	mended and are the bas	d by ANNEXES, i.e. she sis for this report and/or 07 of the Administrative	sheets containing	rectifications made	rawings which have before this Authority
The	e ann	exes consist of a total of	sheets			
1116	e aiiii	exes consist of a total of	5 ,10010.			
3. This	report	contains indications rela	ating to the following item	ns:		
	\boxtimes	Basis of the report				
11		Priority				
111	\boxtimes	Non-establishment of o	pinion with regard to no	velty, inventive ste	p and industrial app	licability
l iv		Lack of unity of invention				
V	⊠	Reasoned statement u citations and explanation	nder Article 35(2) with re ons suporting such state	egard to novelty, in ement	ventive step or indu	strial applicability;
V		Certain documents cit	ed			
VII		Certain defects in the i	nternational application			
VIII	VIII Certain observations on the international application					
Date of si	ıbmissi	on of the demand		Date of completion	of this report	
13/01/1	999			û 4. 10.	99	
Name and mailing address of the international Authorized officer				DISOUS NICE		

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Telephone No. +49 89 2399 8638

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European Patent Office D-80298 Munich

preliminary examining authority:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP97/03099

 Basis of the re 	port
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1.	resp	oonse to an invitation	rawn on the basis of (substitute sheets which have been furnished to the receiving Office in on under Article 14 are referred to in this report as "originally filed" and are not annexed to o not contain amendments.):
	Des	cription, pages:	
	1-26	3	as originally filed
	Clai	ms, No.:	
	1-40)	as originally filed
	Dra	wings, sheets:	
	1/5-	5/5	as originally filed
2.	The	amendments have	e resulted in the cancellation of:
		the description,	pages:
		the claims,	Nos.:
		the drawings,	sheets:
3.		This report has be considered to go l	een established as if (some of) the amendments had not been made, since they have been beyond the disclosure as filed (Rule 70.2(c)):
4.	Ado	litional observation	s, if necessary:
111.	. Noi	n-establishment o	f opinion with regard to novelty, inventive step and industrial applicability
			e claimed invention appears to be novel, to involve an inventive step (to be non-obvious), able have not been examined in respect of:
		the entire internat	ional application.
	Ø	claims Nos. 31-40).

because:

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/EP97/03099

X	the said international application, or the said claims Nos. 31-40 relate to the following subject matter which does not require an international preliminary examination (<i>specify</i>):
	see separate sheet
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
	no international search report has been established for the said claims Nos

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes: Claims

Claims 1-40 No:

Inventive step (IS)

Yes: Claims

No: Claims 1-40

Industrial applicability (IA)

Yes:

Claims 1-30

Claims No:

2. Citations and explanations

see separate sheet

International application No. PCT/EP97/03099

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Claims 31-40 relate to a method for medical treatment of the human or animal body.

٧

(N) A drug targeting system for administration to a mammal comprising nanoparticles made of a polymeric material, said nanoparticles comprising said polymeric material, one or more physiologically effective substance(s) to be delivered to said mammal and one or more stabilizer(s) for said nanoparticles allowing targeting of said physiologically effective substance(s) to a specific site within or on a mammalian body, and a physiologically acceptable carrier and/or diluent allowing the transport of said nanoparticles to the target within said mammal after administration, as defined in claims 1 to 14 of the present application, is already disclosed in documents WO95/22963 (D1), WO94/15590 (D2), EP-A-0 330 180 (D3), EP-A-0 486 959 (D4) and FR-A-2 612 400 (D5). The same applies to the method for preparing said drug targeting systems (claims 15-30) and to the use of said drug targeting system for the preparation of a medicament (claims 31-37) and to the method as defined in claims 38 to 40 of the present application. The relevant passages are: D1; page 7, lines 8-13; page 9 -page 13; examples 1, 2; claims 1-30 -- D2; page 1, lines 5-8; page 2, line 3-4, 25-30; page 4, lines 13-15; page 5, lines 7-10; page 6, line 22 - page 7, line 2; page 7, lines 20-23; page 9, line 28 - page 10, line 14; example 8 -- D3; abstract; page 4, lines 8-17; page 5, lines 2-25; example 1 -- D4; abstract; page 3, line 43; page 4, lines 6-7; examples; claims 1-6 -- D5; abstract; page 3, line 39 - page 4, line 6; page 8, line 37 - page 9, line 27; page 9, lines 36-38; claims 2,9,14 and 15. The stabilizers used according to the present application are defined in claims 9 to 13 and in the description page 18, last paragraph to page 19, third paragraph. Such substances are disclosed in the documents D1 to D5 mentioned above. The expression "... and one or more stabilizer(s) for said nanoparticles allowing targeting of said physiologically effective substance(s) to a specific site within or on a mammalian body;" in claim 1, characterises the invention by indication of the result to be achieved (cf. description, page 4, paragraph 3), and does not imply any technical feature which would distinguish the claimed subject-matter from that known from the prior art (Guidelines C-IV 7.6 PCT).

INTERNATIONAL PRELIMINARY InterEXAMINATION REPORT - SEPARATE SHEET

- (IS) The question Is there inventive step only arises if there is novelty. Moreover, it appears that the problem which faced the skilled man at the priority date of the present Application (description page 4, last paragraph) has already been described and solved in document D1 (D1; page 5, paragraph 3 to page 6, paragraph 4).
- (IA) The industrial applicability is beyond any doubt.

Industrial applicability of claims 31-40

The wording of claims 31-37 "Use of the drug targeting system in the preparation of a medicament allowing one or more physiologically effective substance(s) to be targeted to a specific site within or on a mammalian body" is not clearly directed to the use of said system for the preparation of a medicament. The claimed use in the preparation of a medicament is still directed to the medicament as such. However, the use of a medicament allowing one or more physiologically effective substance(s) to be targeted to a specific site within or on a mammalian body, relates to a method for medical treatment of the human or animal body. Claims 38-40 directly relate to a method for medical treatment of the human or animal body.

For the assessment of the present claims 31-40 on the question whether they are industrially applicable no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims directed to the use of a compound in medical treatment, but may allow, however, claims directed to a known compound for first use in medical treatment and the use of such a compound <u>for</u> the manufacture of a medicament for a new medical treatment.





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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	(Form PCT/ISA/2	of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
97/08217 WO	ACTION	(Fadical Digita Date (day/magth/gag)
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/EP 97/03099	13/06/1997	
Applicant		
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MEDINOVA MEDICAL CONSUL	TING GMBH et al.	
	peen prepared by this International Searching Autl g transmitted to the International Bureau.	hority and is transmitted to the applicant
This International Search Report cons X It is also accompanied by a o	ists of a total of3 sheets. copy of each prior art document cited in this report	
Certain claims were found	unsearchable (see Box I).	
2. Unity of Invention is lacking	g(see Box II).	
	contains disclosure of a nucleotide and/or amin oried out on the basis of the sequence listing	o acid sequence listing and the
	filed with the international application.	
	furnished by the applicant separately from the inte	rnational application,
	but not accompanied by a statement to the matter going beyond the disclosure in the	
	Transcribed by this Authority	
4. With regard to the title,	the text is approved as submitted by the applicant	
	the text has been established by this Authority to re	
DRUG TARGETING SYSTI	EM, METHOD OF ITS PREPARATION	AND ITS USE
	•	
5. With regard to the abstract,	the text is approved as submitted by the applicant	•
	the text is approved as submitted by the applicant the text has been established, according to Rule 3	
	Search Report, submit comments to this Authority	the date of mailing of this International
6. The figure of the drawings to be p	oublished with the abstract is:	
Figure No	as suggested by the applicant.	X None of the figures.
	because the applicant failed to suggest a figure.	
	because this figure better characterizes the inventi	ion.
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A. CLASSI IPC 6	FICATION OF SUBJECT MATTER A61K9/51				
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According to	o International Patent Classification(IPC) or to both national classifica	ation and IPC			
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Minimum do	ocumentation searched (classification system followed by classification $A61K$	on symbols)			
2, 3					
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Electronic d	ata base consulted during the international search (name of data base	se and, where practical, search terms used)			
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	ENTS CONSIDERED TO BE RELEVANT				
Category °	Citation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.		
χ	WO 95 22963 A (MEDINOVA MED CONSU	ILTING	1-40		
^	GMBH) 31 August 1995	,211114	1 10		
	cited in the application	· ·	•		
	see abstract				
	see page 7, line 8-13 see page 9 - page 13				
	see example 2	·			
	see claims				
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X Furti	her documents are listed in the continuation of box C.	X Patent family members are listed in	annex.		
° Special ca	stegories of cited documents :	"T" later document published after the intern			
	ent defining the general state of the art which is not lered to be of particular relevance	or priority date and not in conflict with the cited to understand the principle or the			
"E" earlier o	document but published on or after the international	invention "X" document of particular relevance; the cla			
	ent which may throw doubts on priority claim(s) or	cannot be considered novel or cannot be involve an inventive step when the doc			
	is cited to establish the publicationdate of another n or other special reason (as specified)	"Y" document of particular relevance; the cla cannot be considered to involve an inve			
	ent referring to an oral disclosure, use, exhibition or means	document is combined with one or mor ments, such combination being obvious			
	ent published prior to the international filing date but nan the priority date claimed	in the art. "&" document member of the same patent fa	amily		
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. 2	February 1998	10/02/1998			
Name and r	Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2				
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	Fax: (+31-70) 340-3016	La Gaetana, R			

		PC1/EP 9//03099
	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 15590 A (ABACOL LTD ;DYATLOV VALERY A (RU); KATZ GEORGY ARKADIEVICH (RU)) 21 July 1994 see abstract see page 1, line 5-8 see page 2, line 3-4 see page 2, line 25-30 see page 4, line 13-15 see page 5, line 7-10 see page 6, line 22 - page 7, line 2 see page 7, line 20-23 see page 9, line 28 - page 10, line 14 see example 8	1-12,15, 18,20-25
X	EP 0 330 180 A (BIOMATERIALS UNIVERSE INC) 30 August 1989 see abstract see page 4, line 8-17 see page 5, line 2-15 see example 1	1-6, 8-12,15, 18-40
X	EP 0 486 959 A (VECTORPHARMA INT) 27 May 1992 see abstract see page 3, line 43 see page 4, line 6-7 see examples see claims 1-6	1-6, 8-12,15, 18-40
X	FR 2 612 400 A (CENTRE NAT RECH SCIENT; UNIV ANGERS (FR)) 23 September 1988 see abstract see page 3, line 39 - page 4, line 6 see page 8, line 37 - page 9, line 27 see page 9, line 36-38; claims 2,9,14,15	1-5, 8-12,15, 18-25, 28-30
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FR 2612400 A	23-09-88	NONE	

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 9/51	A1	 (11) International Publication Number: WO 98/56361 (43) International Publication Date: 17 December 1998 (17.12.98)
 (21) International Application Number: PCT/EP (22) International Filing Date: 13 June 1997 ((71) Applicant (for all designated States except US): MEI MEDICAL CONSULTING GMBH [DE/DE]; Han D-39116 Magdeburg (DE). (72) Inventors; and (75) Inventors/Applicants (for US only): SABEL, Berr [DE/DE]; Kronprinzessinnenweg 13, D-14109 Ber SCHROEDER, Ulrike [DE/DE]; Am Sülzehang 7, Dodendorf (DE). (74) Agents: KOEPE, Gerd, L. et al.; Blumbach, Kramer & Radeckestrasse 43, D-81245 München (DE). 	13.06.9 DINOV sapark shard, A rlin (DE D-391	BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.

(54) Title: DRUG TARGETING SYSTEM, METHOD OF ITS PREPARATION AND ITS USE

(57) Abstract

A composition and method of fabrication are presented with which nanoparticles may be used as a tool to deliver drugs to a specific target within or on a mammalian body. Specifically, by using stabilizers other than Dextran 70.000 during the polymerization process, according to the present invention, surfactants, which were deemed necessary coating material in the prior art, are no longer required. This is a significant simplification of the fabrication procedure. Many substances are useful as stabilizers, but the preferred stabilizers comprise Dextran 12.000 or polysorbate 85. In the present invention a drug is either incorporated into or adsorbed onto the stabilized nanoparticles. This drug/nanoparticle complex is then administered to the organism on any route such as by oral application, injection or inhalation, whereupon the drug exerts its effect at the desired site of pharmacological action. In a novel medical treatment process, the drug/nanoparticle complex may be administered preferably either by intravenous injection or by oral application. The resulting drug action, which does not occur or which occurs only to an insufficient extent when the drug is administered alone, shows that when linked to said nanoparticles drugs can reach a specific target within or on the mammalian body. The usefulness of the present invention as a universal approach to deliver any drug or diagnostic agent to a specific target within or on the mammalian body was demonstrated by experiments showing an unexpected transfer of the drug across the blood brain barrier.

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Int. donal Application No PCT/EP 97/03099

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61K9/51					
According to International Patent Classification (IPC) or to both national classification and IPC					
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	cumentation searched (classification system followed by classification A61K	symbols)			
Documentat	ion searched other than minimumdocumentation to the extent that su	ch documents are included in the fields search	ned		
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C. DOCUME	ENTS CONSIDERED TO BE RELEVANT				
Category °	Citation of document, with indication, where appropriate, of the relev	vant passages	Relevant to claim No.		
X	WO 95 22963 A (MEDINOVA MED CONSU GMBH) 31 August 1995 cited in the application see abstract see page 7, line 8-13 see page 9 - page 13 see example 2 see claims	/	1-40		
X Furti	her documents are listed in the continuation of box C.	X Patent family members are listed in a	annex.		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filling date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed 2 February 1998 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined to involve an inventive step when th		e application but ny underlying the med invention e considered to ment is taken alone imed invention ntive step when the other such docu- to a person skilled mily			
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INTERNATIONAL SEARCH REPORT



Intensional Application No PCT/EP 97/03099

	alion) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to claim No.	
Category "	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
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	see abstract see page 3, line 43 see page 4, line 6-7 see examples see claims 1-6		
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	see abstract see page 3, line 39 - page 4, line 6 see page 8, line 37 - page 9, line 27 see page 9, line 36-38; claims 2,9,14,15		



* Information on patent family members

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